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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,895	01/16/2007	Tushar A. Kshirsagar	C1271.70050US01	1940

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EXAMINER	
JARRELL, NOBLE E	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
04/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,895	KSHIRSAGAR ET AL.	
	Examiner	Art Unit	
	NOBLE JARRELL	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4-8,13,15-20 and 23-41* is/are pending in the application.

4a) Of the above claim(s) *6-8,17,18,30,31 and 36-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4,5,13,15,16,19,20,23-29,32-35,40 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/19/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I in the reply filed on 9 March 2009 is acknowledged.

2. Claims 6-8, 17-18, 30-31, and 36-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9 March 2009.

Claim Objections

3. Claims 2, 4-5, 13, 15-16, 19-20, 24-29, 32-35, and 41 are objected to because of the following informalities: they contain non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 25-27, 35, and 41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *in vitro* induction of cytokine biosynthesis, does not reasonably provide enablement for *in vivo* induction of

cytokine biosynthesis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

> The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Consideration of the relevant factors sufficient to establish a *prima facie* case for lack of enablement is set forth herein below:

(1) The nature of the invention and (2) the breadth of the claims:

> The claims are drawn to a method of inducing cytokine biosynthesis in animals with a compound that is partly composed of a 9,10,11,12-tetrahydro-8*H*-[1,4]diazepino[1',2':1,2]imidazo[4,5-*c*]quinolin-6-amine ring. Thus, the claims taken together with the specification imply that compounds of the instant application can induce cytokine biosynthesis *in vitro* or *in vivo* in the treatment of a disease.

(3) The state of the prior art / (4) the predictability or unpredictability of the art:

Regan et al. (*Virology*, **2009**, 135-143) teach that modulation of pro-inflammatory cytokine production may possess therapeutic benefits in cats (page 141). This teaching suggests that future research is needed to determine if induction of cytokine biosynthesis is of real therapeutic value.

(5) The relative skill of those in the art:

Those of relative skill in the art are those with level of skill of the authors of the references cited to support the examiner's position. The relative skill of those in this art is MD's, PhD's, or those with advanced degrees and the requisite experience in induction of cytokine biosynthesis.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for *in vitro* induction of cytokine biosynthesis (pages 183-184).

However, the specification does not provide guidance for *in vivo* induction of cytokine biosynthesis.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to claims 25-27, 35, and 41 and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2, 4-5, 13, 15-16, 19-20, 24-29, 32-35, and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are unclear due to several factors. The first factor is any occurrence of heteroaryl, heteroarylalkenyl, heteroaryloxyalkylenyl, alkylheteroarylenyl, or heterocyclyl. Each of these groups is unclear because an open-ended definition is provided in the specification (page 27, line 23 to page 28, line 13). One of these heterocyclic rings (if it were azepane or azocane) could control classification (instead of the 1,4-diazepane ring). The instance of Y' when it is N-R_7-N-Q (and another R_7 is couples the nitrogen atoms) is unclear because this ring represents 36 rings (6 possibilities for each instance of variable R_7). In an analysis of variable R_5, possibilities 3 and 4 (the instances with a N-$(CH_2)_a$-A-$(CH_2)_b$ ring are unclear. These rings represent numerous rings because of the four meanings for variable A (C, O, S, or N) and the proviso that the sum of variables a and b is less than or equal to 7 (a +b <=7). These rings can be as simple as aziridine or as complex as morpholine. Claim 26 is unclear because it is

unclear what viral disease applicants are intending to treat with compounds of the instant application. Only a broad, open-ended definition is provided in the application (page 58, line 29 to page 59, line 5). Claim 27 is indefinite because an open-ended definition for "neoplastic diseases" is provided in the specification (page 59, lines 16-20).

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 2, 4, 5, 13, 15-16, 19-20, 23-29, 32-35, and 40-41 are provisionally rejected on the ground of nonstatutory double patenting (obvious-type) as being

unpatentable over claims 5-8, 18, 56, 67-70, 73, and 74 of copending Application No. 11/813039. Although the conflicting claims are not identical, they are not patentably distinct from each other because example 24 (page 59 of copending application 11/813039, PGPub 20080269192) is encompassed by the specified claims in both applications.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Determining the scope and contents of the copending application

In example 24 of copending application 10/813039, variable Y is SO_2Me, X is a bond, X' is ethylene, and variables R_{B1} and R_{A1} form a phenyl ring. This compound is being used in the same method of use as compounds of application 10/596895 (see abstract of 10/813039).

Ascertaining the differences between the copending application and the claims at issue

In application 10/596895, the 7-posiiton of the 1,4-diazapane ring is a CH_2 group. In application 11/813039, the 7-position of the 1,4-diazepane ring is a CH(Me) group.

Resolving the level of ordinary skill in the pertinent art

Those of relative skill in the art are those with level of skill of the authors of the references cited to support the examiner's position. The relative skill of those in this art is MD's, PhD's, or those with advanced degrees and the requisite experience in preparation of compounds with a 9,10,11,12-tetrahydro-8*H*-[1,4]diazepino[1',2':1,2]imidazo[4,5-*c*]quinolin-6-amine ring.

Considering objective evidence present in the application indicating obviousness or nonobviousness

The only difference between example 24 of 10/813039 and a compound of claim 1 of application of 10/596895 is the carbon atom of the 7-position of the 1,4-diazepane ring. In the instant application, the carbon atom is a methylene (CH_2) group. In application 11/813039, the carbon group is a CH(Me) group. These two groups only differ by a methylene group because the difference between a hydrogen substituent and a CH_3 substituent is CH_2. Compounds of both applications are being used for the same purpose, the induction of cytokine biosynthesis. One of ordinary skill in the art would conclude that example 24 has

a reasonable expectation of success based upon the teachings of application11/813039. Thus, claims 5-8, 18, 56, 67-70, 73, and 74 of copending Application No. 11/813039, in light of example 24 (which it is encompassed by the specified claims in both applications) renders claims 2, 4, 5, 13, 15-16, 19-20, 23-29, 32-35, and 40-41 of application 10/596895 obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NOBLE JARRELL whose telephone number is (571)272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624